

# Exhibit 29

**PEEK to PE Junction Strength Experiment, 5/5/94**  
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**Objective:** To determine the effect of some critical process and design conditions on the intermediate junction from PEEK to polyethylene.

**Background:** The PEEK to polyethylene junction on the outer shaft of the coaxial OTW catheter is located about 30 cm from the balloon. This junction must have enough strength to resist pulling apart. Three parameters which are thought to affect the tensile strength of the lap joint are the bond length, the type of adhesive, and whether or not the polyethylene is plasma treated.

**Description:** The three parameters are systematically varied in a Designed Experiment to determine their effect. The value of these parameters is as follows:

Code	Parameter	Minus (-)	Plus (+)
A	Plasma treated PE	No	Yes
B	Adhesive type	UV 350	FMD-14
C	Bond length	2 mm	4 mm

A full factorial design with four replicates is used in Design Ease to give a 32 run experiment. The actual runs are included in the test matrix (Table 1).

**Materials:**

PEEK tubing, .0325"/.039", Peek 381G, Ap 02-149

Alathon 6210 PE tubing, .032"/.038", Ext. # 12-083

UV curable adhesive No. 35041, RM60562, lot # 13566

Cyanoacrylate adhesive, FMD-14, RM64232, lot # 13273

.031", .039" Teflon coated mandrels

Hot box

Autonecker

Adhesives area plasma chamber, Plasma Science PS500 (Process 8, 100% Argon, 7 min., 200 watts)

Dual Wand UV Cure Fixture, UVEXS SCU110 adjusted to 100 mw/cm<sup>2</sup>, 365 nm, 60 sec

**Build Procedure:**

The Alathon PE is prepared by cutting samples at least 4" long and flaring one end for the junction. This flaring is done by heating a .039" teflon coated mandrel in a hot box at about 430 F and then inserting the mandrel into the tubing. The length of the flared section is then trimmed to the desired bond length from the table above. The units which require plasma treating are plasma treated and stored about 1 day until the joints are done.

The PEEK is prepared by necking one end of the sample onto a .031" teflon coated mandrel in the joint area for 5 - 7 mm. The necking is done on an autonecker at 500 F. The samples using UV adhesive are necked to .037" OD to allow a .002" diametrical clearance for the adhesive, and the samples using the FMD-14 adhesive are necked to .038" to allow a .001" diametrical clearance. Since the tolerance of the tubing even at +/- .0005" tolerance will cause substantial variability in the gap width, this must be checked before applying the adhesive. If the parts are too tight, they will not be used, but if they are too large it is difficult to detect. The criteria used will be if the adhesive in the joint has a uniform appearance, it will be acceptable.

The PEEK samples are then cleaned in an ultrasonic bath of 70% IPA and 30% water for at least 3 minutes. The excess is blown out of the ID with air and the samples are then air dried for at least 15 minutes to allow for complete drying.

The bonds are then performed in the order shown in the test matrix in Table 1. Each adhesive is used separately without alternating adhesives to simplify the fixturing; consequently, the test matrix is used twice, once for each adhesive. This is because any interactions each adhesive may have with the other variables is independent of those of the other adhesive.

The bonds are done using a support mandrel to hold the joint straight. The UV adhesive is applied using a mandrel to apply the adhesive to the PEEK surface and then sliding the two sides together to the appropriate bond length and rotating the parts to distribute the adhesive. Once the correct bond length is obtained, the adhesive is cured. For the FMD-14 wicking adhesive, the parts are slid together and placed on the adhesive bonding fixture in the adhesives lab. The correct bond length is set and then the adhesive is applied and distributed at the interface of the two tubes. The bond length should be 1.5 - 2.0 mm for the 2 mm length and 3.5 - 4.0 for the 4 mm length. The samples should all be clearly labeled with the run number in Table 1 and stored for testing. Note: Kim Nguyen performed all of the builds.

**Test Procedure:** The testing was performed three days after the samples were built. The samples are all tensile tested on the Instron in the order given in the test matrix. The testing is done at room temperature using a 2 inch gauge length and a crosshead speed of 2"/min. The maximum load is used to analyze the results. Note: Pat Urasaki performed the testing.

#### **Results:**

There were two data points that were discarded in the analysis as outliers. The two runs are shown in Figures 1 and 2. The adhesive bond of the joint was not uniform and was suspect, so there is just cause for discarding them. Table 2 contains the complete data set and indicates the runs which were discarded.

Table 1 includes some qualitative comments about the failure mode during testing. Those runs in which the joint pulled apart at the adhesive and neither tubing broke are indicated as "joint" or "joint failed." Those runs in which the PE tubing broke, but the adhesive joint was intact are indicated as "brk PE." Those runs in which the PE tubing broke, but at least some of the PE was left bonded to the PEEK are shown as "1/2 joint + 1/2 PE brk."

The half-normal probability chart in Figure 3 shows the variables which are selected for the analysis. Table 3 contains the analysis of variance (ANOVA) for the experiment. The R-squared is 0.91 which shows that experiment included all of the critical factors. The variability in the gap for adhesive must therefore have been at the most a small effect. All three factors, plasma, adhesive and bond length, are statistically significant. The diagnostics for the experiment in Figures 4 - 7 look fine.

The plasma treatment increases the joint strength by .58 pounds as shown in Figure 8. This is a substantial increase and demonstrates the value of plasma treating polyethylene. There are also five runs outlined in Table 1 (Runs 1, 4, 14, 18 & 28) in which the joint was stronger than the polyethylene, so the polyethylene tubing broke before the joint could pull apart. These joints all used plasma treating to obtain this strength; none of the untreated samples did this. There were also the two samples which were discarded as being outliers that had unusually low pull strengths. Neither of these units were plasma treated. Even though these units were rejected because of inadequacy of the joint, the lack of plasma treating may have contributed to this. Feedback from Kim Nguyen, who built the samples, indicated that the plasma treated units were much easier to build and obtain a satisfactory appearance. The plasma treating, although it may not be required to achieve adequate strength, certainly increases both the joint strength and the quality of the bond.

The adhesive made only a small difference in the joint strength (Figure 9). The average strength of the UV adhesive is .12 pounds greater than the FMD-14. This is not a very big impact, so the greater gap required for the UV adhesive may not be justified depending on the joint requirements. The same five runs in which the polyethylene broke before the joint pulled apart not only were plasma treated, they also all used the UV adhesive. This is a more qualitative measure of the difference in the adhesives, but the UV adhesive seems to have a greater potential to give a very strong joint. The joint was stronger than the polyethylene in these runs, so the test is actually giving the polyethylene shaft strength; the joint strength is greater than this data indicates. It should also be noted that the two units which were outliers for low strength both used the UV adhesive, but this may be a coincidence.

Increasing the bond length from 2 to 4 mm increases the bond strength by 0.37 pounds. This significant change indicates that the design of the length of the bond is an important parameter for meeting the joint strength.

**Summary:**

**Conclusions:**

1. Plasma treating the polyethylene increases the strength of the joint by 0.58 pounds and improves the ability to make good joints. In five of the plasma treated joints, the polyethylene broke before the joint failed, so plasma treating may actually increase the bond strength more than 0.58 pounds.
2. Increasing the bond length from 2 to 4 mm increases the joint strength by 0.37 pounds.
3. The UV adhesive only increases the joint strength by 0.12 pounds, but this difference is limited by the polyethylene shaft strength. In five of the UV bonds, the polyethylene shaft broke before the joint failed, so the UV adhesive may increase the bond strength by more than 0.12 pounds.
4. The strongest joint in the study used plasma treatment and the UV adhesive. In five of the eight joints with this combination, the polyethylene broke before the joint failed, so the true bond strength is higher than the test data shows.

**Recommendations:**

1. To achieve the strongest, highest quality joint possible, the plasma treating should be used. It also makes the bonding process easier and more forgiving to process variability.
2. The length of the bond should be maximized to achieve the highest bond strength.
3. The UV adhesive should be used to maximize the strength of the bond, but the magnitude of the benefit from doing this is uncertain.
4. The conditions which should be used to make the bond depend entirely on the requirements of the joint, so the exact requirements must be clearly defined before a decision can be made on using any combination of the tested factors.

Figure 8  
DESIGN-EASE Analysis

Tensile  
A= 1.828  
A+ 2.207

Fac Value  
A= no  
A+ yes

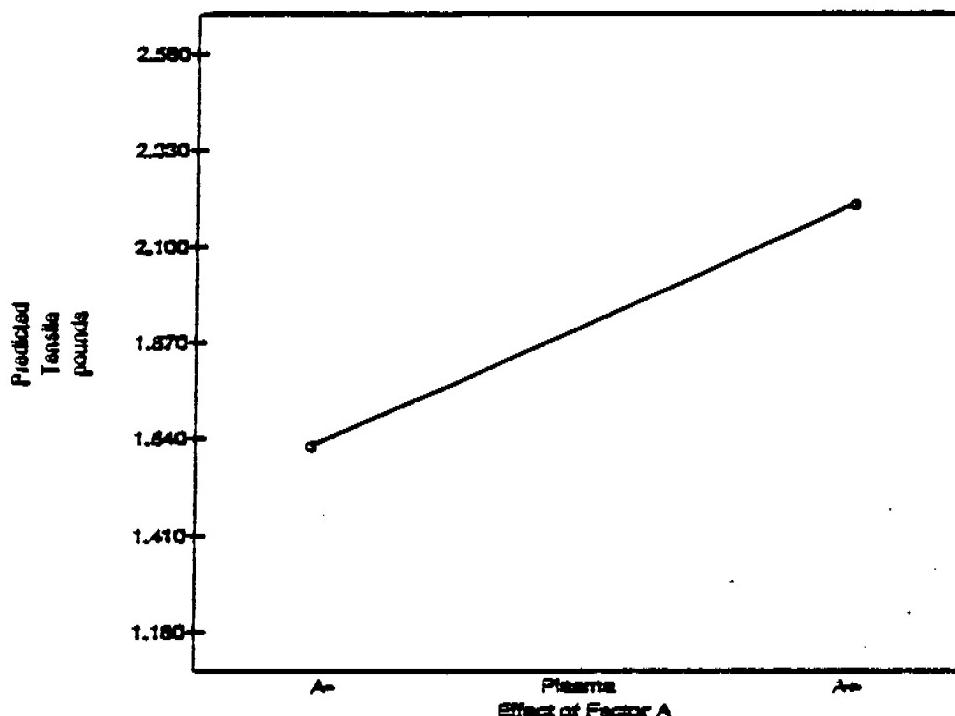
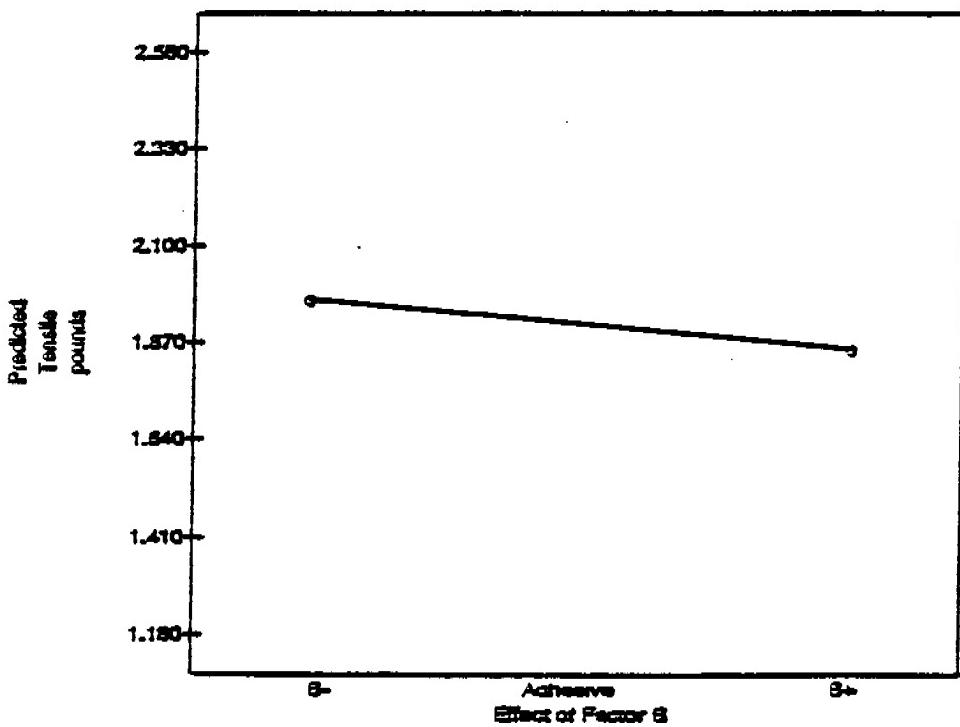


Figure 9  
DESIGN-EASE Analysis

Tensile  
B- 1.978  
B+ 1.868

Fac Value  
B- UV350  
B+ PMD-14



## **ACTION ITEMS - PEEK TECHNICAL REVIEW**

- Extrusion Process Optimization
- Tubing Source Decision Plan
  - Cost Comparisons
  - Quality Control Comparisons
  - Other Issues
- Supplier Agreements
  - Resin
  - Tubing (if Acutech)
- Plans for Equipment Acquisitions
- Radiation Effects Study
- Other